

116TH CONGRESS
1ST SESSION

H. R. 4393

To amend title XIX of the Social Security Act to provide for a State option under the State Medicaid plan to provide DNA sequencing clinical services for certain children, provide for a study by the National Academy of Medicine on the use of genetic and genomic testing to improve health care, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2019

Mr. SWALWELL of California (for himself, Mr. FITZPATRICK, Mr. GALLEGOS, Mr. ROUDA, and Ms. NORTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title XIX of the Social Security Act to provide for a State option under the State Medicaid plan to provide DNA sequencing clinical services for certain children, provide for a study by the National Academy of Medicine on the use of genetic and genomic testing to improve health care, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Advancing Access to
5 Precision Medicine Act”.

1 **SEC. 2. STATE OPTION TO PROVIDE DNA SEQUENCING**

2 **CLINICAL SERVICES FOR CERTAIN CHIL-**
3 **DREN.**

4 Title XIX of the Social Security Act (42 U.S.C. 1396
5 et seq.) is amended by adding at the end the following
6 new section:

7 **“SEC. 1947. STATE OPTION TO PROVIDE DNA SEQUENCING**
8 **CLINICAL SERVICES FOR CERTAIN CHIL-**
9 **DREN.**

10 “(a) IN GENERAL.—Notwithstanding section
11 1902(a)(1) (relating to statewideness), section
12 1902(a)(10)(B) (relating to comparability), and any other
13 provision of this title for which the Secretary determines
14 it is necessary to waive in order to implement this section,
15 beginning on the first day of the first fiscal quarter that
16 begins on or after the date of the enactment of this sec-
17 tion, a State, at its option as a State plan amendment,
18 may provide for medical assistance under this title to an
19 eligible individual for purposes of providing the individual
20 with DNA sequencing clinical services.

21 “(b) PAYMENTS.—

22 “(1) IN GENERAL.—A State shall provide a
23 health care provider (as defined by the State) with
24 payments for the provision of DNA sequencing clin-
25 ical services to any eligible individual. Payments
26 made to a health care provider for such services

1 shall be treated as medical assistance for purposes
2 of section 1903(a), except that, during the first 8
3 fiscal year quarters that the State plan amendment
4 is in effect, the Federal medical assistance percent-
5 age applicable to such payments shall be equal to 75
6 percent.

7 “(2) METHODOLOGY.—The State shall specify
8 in the State plan amendment the methodology the
9 State will use for determining payment for the provi-
10 sion of DNA sequencing clinical services. Such meth-
11 odology for determining payment shall be established
12 consistent with section 1902(a)(30)(A).

13 “(3) PLANNING GRANTS.—

14 “(A) IN GENERAL.—Beginning on the date
15 described in subsection (a), the Secretary may
16 award planning grants to States for purposes of
17 developing a State plan amendment under this
18 section. A planning grant awarded to a State
19 under this paragraph shall remain available
20 until expended.

21 “(B) STATE CONTRIBUTION.—A State
22 awarded a planning grant shall contribute an
23 amount equal to the State percentage deter-
24 mined under section 1905(b) for each fiscal
25 year for which the grant is awarded.

1 “(c) HOSPITAL REFERRALS.—A State shall include
2 in the State plan amendment a requirement for any hos-
3 pital that is a participating provider under the State plan
4 (or a waiver of such plan) to establish procedures for re-
5 ferring any eligible individual who seeks or needs treat-
6 ment in a hospital emergency department to a health care
7 provider who is qualified (as determined by the State) to
8 provide DNA sequencing clinical services.

9 “(d) REPORTS BY STATES.—Not later than three
10 years after the date on which the State plan amendment
11 under this section is approved, a State shall submit a re-
12 port to the Administrator of the Centers for Medicare &
13 Medicaid Services and the Administrator of the Health
14 Resources and Services Administration on—

15 “(1) the extent to which DNA sequencing clin-
16 ical services reduce health disparities; and

17 “(2) the extent to which coverage under the
18 State plan (or a waiver of such plan) impedes the
19 use of genetic and genomic testing that may improve
20 clinical outcomes for eligible individuals enrolled in
21 the State plan (or under a waiver of such plan).

22 “(e) REPORTS BY HEALTH CARE PROVIDERS.—As a
23 condition for receiving payment for DNA sequencing clin-
24 ical services provided to an eligible individual, a health
25 care provider shall report to the State, in accordance with

1 such requirements as the Secretary shall specify, on all
2 applicable measures for determining the quality of such
3 services.

4 “(f) DEFINITIONS.—In this section:

5 “(1) ELIGIBLE INDIVIDUAL.—The term ‘eligible
6 individual’ means an individual who—

7 “(A) is eligible for medical assistance
8 under the State plan (or a waiver of such plan);

9 “(B) is under the age of 21 (or, at the op-
10 tion of the State, under the age of 20, 19, or
11 18 as the State may choose), or in the case of
12 an individual described in section
13 1902(a)(10)(A)(i)(IX), under the age of 26;

14 “(C) has been referred or admitted to a
15 pediatric intensive care unit for a chronic or
16 undiagnosed disease;

17 “(D) has been seen by at least one medical
18 specialist for such chronic or undiagnosed dis-
19 ease; and

20 “(E) is suspected by at least one medical
21 specialist to have a pediatric-onset genetic dis-
22 ease.

23 “(2) DNA SEQUENCING CLINICAL SERVICES.—
24 The term ‘DNA sequencing clinical services’, with
25 respect to an eligible individual—

1 “(A) means a determination of an exact
2 sequence of deoxyribonucleic acid bases in the
3 genome of such individual, and, if for the sole
4 benefit of the individual, a biological parent of
5 such individual for the purpose of determining
6 whether one or more potentially disease-causing
7 genetic variants are present in the genome of
8 such individual or such biological parent; and

9 “(B) includes—

10 “(i) sequencing of the entire genome,
11 of the exome, of a panel of genes, or other
12 regions of the genome; and

13 “(ii) any analysis, interpretation, and
14 data report derived from such sequenc-
15 ing.”.

16 **SEC. 3. NATIONAL ACADEMY OF MEDICINE STUDY.**

17 (a) IN GENERAL.—Not later than 4 years after the
18 date of the enactment of this Act, the Secretary of Health
19 and Human Services shall enter into an arrangement with
20 the National Academy of Medicine under which the Acad-
21 emy agrees to study—

22 (1) how genetic and genomic testing may im-
23 prove preventative care and precision medicine;

24 (2) how genetic and genomic testing may re-
25 duce health disparities;

(B) supporting the collection of evidence for the clinical utility and appropriate use of genetic and genomic tests; and

(C) improving access to genetic counselors, pathologists, and other relevant professions, including strengthening related workforce education and training efforts;

1 genomic testing and improved clinical outcomes for
2 beneficiaries; and

3 (C) how the Centers for Medicare & Medicaid
4 Services may make coverage determinations that
5 better suit a precision medicine approach to treat-
6 ment; and

7 (5) how genetic and genomic testing may im-
8 prove health outcomes for all populations in the
9 United States, including—

10 (A) individuals with a rare disease, includ-
11 ing—

12 (i) a metabolic disease;
13 (ii) a hereditary cancer syndrome; and
14 (iii) a neurologic disease with known
15 treatments; and

16 (B) special populations, including—

17 (i) infants and children;
18 (ii) critically ill (non-infectious and
19 non-trauma) patients;

20 (iii) transplant patients;

21 (iv) individuals with cardiac disease;
22 and

23 (v) individuals with, or who have a
24 family history of, a birth defect or develop-
25 mental disability.

1 (b) REPORT.—

2 (1) IN GENERAL.—The arrangement under sub-
3 section (a) shall provide for the National Academy
4 of Medicine to submit, not later than 6 years after
5 the date of enactment of this Act, a report on the
6 results of the study under subsection (a) to—

7 (A) the Secretary of Health and Human
8 Services;

9 (B) the Committee on Ways and Means
10 and the Committee on Energy and Commerce
11 of the House of Representatives; and

12 (C) the Committee on Finance and the
13 Committee on Health, Education, Labor, and
14 Pensions of the Senate.

15 (2) CONSULTATION.—The arrangement under
16 subsection (a) shall provide for the National Acad-
17 emy of Medicine, in developing the report required
18 by paragraph (1), to consult with physicians, other
19 health professionals, health educators, health profes-
20 sional organizations, relevant companies, patients,
21 patient organizations, the Health Resources and
22 Services Administration, the National Cancer Insti-
23 tute, the National Institutes of Health, the Agency
24 for Healthcare Research and Quality, and the Cen-
25 ters for Medicare & Medicaid Services.

1 (3) USE OF INFORMATION.—The National
2 Academy of Medicine shall, to the extent possible, in
3 conducting the study under subsection (a), utilize in-
4 formation included in the reports submitted pursu-
5 ant to subsections (d) and (e) of section 1947 of the
6 Social Security Act (as added by section 2).

